What is the translation of HSCL-25 in Galician; A consensus procedure by Delphi-round and Forward-Backward translation

Arthur Augustin

UNIVERSITÉ DE BREST - BRETAGNE OCCIDENTALE

Faculté de Médecine & des Sciences de la Santé

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Par **Mr AUGUSTIN Arthur**

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Présentée par Mr le Professeur Jean-Yves LE RESTE

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What is the translation of HSCL-25 in Galician;

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Mr AUGUSTIN Arthur, Interne en médecine générale.

Fait à BREST, le

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Le Président du Jury

A BREST, le

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Mon premier souci sera de rétablir, de préserver ou de promouvoir la santé dans tous ses éléments, physiques et mentaux, individuels et sociaux.

Je respecterai toutes les personnes, leur autonomie et leur volonté, sans aucune discrimination selon leur état ou leurs convictions. J'interviendrai pour les protéger si elles sont affaiblies, vulnérables ou menacées dans leur intégrité ou leur dignité. Même sous la contrainte, je ne ferai pas usage de mes connaissances contre les lois de l'humanité.

J'informerai les patients des décisions envisagées, de leurs raisons et de leurs conséquences. Je ne tromperai jamais leur confiance et n'exploiterai pas le pouvoir hérité des circonstances pour forcer les consciences.

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Admise dans l'intimité des personnes, je tairai les secrets qui me seront confiés.

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List of Abbreviations

DSM: Diagnostic and Statistical Manual of Mental Disorders

EGPRN: European General Practice Research Network

GP: General Practice

GPs: General Practitioners

FPDM: Family Practice Depression and Multimorbidity

HSCL-25: Hopkins Symptom Checklist in 25 items

NI: National Investigator

IIT: International Investigation Team

RAND/UCLA: Research ANd Development corporation and the University of California Los Angeles

HSCL-25 Forward-Backward translation to Galician by Delphi Procedure. Third Phase of FPDM

Résumé

Introduction *:* Les médecins généralistes européens sont le premier recours des patients dépressifs. Les patients de plus de 50 ans multi-morbides sont plus à risque d'épisodes dépressifs. Les variations interindividuelles et interculturelles peuvent modifier l'expression des symptômes. En soins primaires, peu d'outils diagnostiques sont adaptés et utilisés.
L'étude Family Practice Depression and Multimorbidity (FPDM) de l'European General Practice Research Network (EGPRN) a pour objectif de sélectionner un outil diagnostique de la dépression en médecine générale. Des recherches européennes collaboratives entre médecins généralistes de différents pays et entre médecins généralistes et psychiatres pourront être réalisées.
Les deux premières étapes ont sélectionné la Hopkins Symptom Checklist en 25-items (HSCL-25) comme la plus appropriée selon les critères d'efficacité, de reproductibilité et d'ergonomie versus DSM.

Objectif *:* L'objectif était de traduire la HSCL-25 en Galicien sans perte de sens mais cette traduction devait être compréhensible par les médecins et les patients, en prenant en compte les particularités culturelles et linguistiques galiciennes.

Méthode *:* Une procédure Delphi adaptée avec traduction Aller-Retour a été utilisée. Une traduction de l'Anglais au Galicien a été soumise par procédure Delphi à un panel d'experts en soins primaires. La traduction retour a été réalisée en aveugle de l'original.

Résultats *:* Le panel d'experts répondait aux critères d'inclusion. La traduction galicienne a été validée après deux tours. La traduction retour en anglais a été produite.

Discussion *:* Le choix d'une méthode de traduction Aller-Retour par procédure Delphi adaptée et la qualité du panel d'experts garantissent une traduction galicienne validée et fiable de la HSCL-25. La prochaine étape est une analyse culturelle de la traduction qui assurera la similitude sémantique entre la version originale et la traduction.

Abstract

Introduction*:* General Practitioners (GPs) are the first port of call for depressive patients in developed countries. The multi-morbid patients over 50 years are more at risk. Inter-individual and intercultural variations may change the symptoms expression. Few diagnostic tools are adapted and used by GPs. Family Practice Depression and Multimorbidity (FPDM) study by European General Practice Research Network (EGPRN) aims to select a depression diagnostic tool in primary care to undertake collaborative research involving GPs and Psychiatrists throughout Europe.
The two previous steps of FPDM found that the Hopkins Symptom Checklist in 25-items (HSCL-25) was the most appropriate tool according to effectiveness, reproducibility and ergonomics criteria, versus DSM.

***Objective**:* This study aimed to translate HSCL-25 in Galician, keeping its meaning. This translation must be understandable by practitioners and patients, according to Galician cultural and linguistic features.

Method: A Delphi method adapted for a Forward-Backward translation was used. The Forward-translation from English to Galician was submitted by Delphi procedure to a panel of primary care experts. The Back-translation was performed following the blind back-translation principle.

***Results**:* The inclusion criteria of panel were followed. The Forward Galician translation was accepted after two rounds. English back-translation was produced blind.

***Discussion**:* The Forward-Backward translation by Delphi method was effective to translate the HSCL-25 to Galician. The experts panel quality ensured a validated and reliable Galician translation. The following step will consist in a cross-cultural check. Similarity of interpretability between the Original and the Back-translation will be analysed.

Introduction

Depression is the second most common chronic disorder in general practice(1) GPs are the first port of call in most European Countries.(2,3) The multi-morbid patients over 50 years are more at risk of depression.(4–10)

Depression is a variable combination of symptoms shared with other mental disorders like contextual distress, anxiety and somatoform disorders. The patient himself experiences difficulties to express his suffering and shows his own illness expression.(11,12)

The difficulties to diagnose and assess the severity of depression lie in this inter-individual variability.(13) Clinicians can overestimate or underestimate the distress level of their patients.(14–16) Those difficulties may lead to inappropriate care and cause public health problems.(17–20) Diagnostic and Statistical Manual of Mental Disorders (DSM) is widely considered as gold standard to diagnose depression(21), but it is rarely used in General practice.(22,23) In addition, General Practitioners (GPs) seem to be uncomfortable with the definition of depression and available diagnostic tools.(13,24–26) Incidence and prevalence rates of depression differ in General practice across Europe(27–31). This is related to complex contextual variations with differences in health care system, in concepts, objectives and practices as well as cultural variations in the expression of the disease.(25,32–38)

European GPs community needs a better knowledge of usable instruments to diagnose depression in adult patients.(32)(24) There is also a need for a European consensus on a diagnostic tool for depression to undertake collaborative research in General practice throughout Europe.(39,40)

The Family Practice Depression and Multi-morbidity study (FPDM) started in 2011.The aim of FPDM study was to select a tool that could be consensually used by GPs to diagnose adult patient's depression and to make it applicable in the participating European countries. In order to be satisfying, it had to be efficient, reliable and easy to use by GPs throughout Europe. This study consisted of four steps.

The first step was a systematic review of literature (SRL), in order to select the candidate tools. The SRL investigated all diagnostic tools that were validated for depression versus DSM, in adult patients excluding pregnant and post-partum women. At the end of this step, seven tools were selected.(41,42)

The second step was a consensus procedure aiming to select a single tool among the seven candidates. The method chosen to reach a consensus was RAND/UCLA (Research ANd Development corporation / University of California Los Angeles) procedure.(43) HSCL-25 was designated to be the most appropriate tool for depression's diagnosis in adult patients in General practice in Europe, according to its criteria combined of effectiveness, reliability and ergonomics.(42)

The third step consisted in translating this tool in the language of each country taking part in the FPDM study, following the same formal consensus method (44), with the support of European General Practice Research Network (EGPRN). The HSCL-25 was used but there is no official and consensual translation available.

In many Spanish regions, the GP and his patient will either communicate in Spanish (Castilian), or in a regional language (as Catalan, Galician…). Since emotional expression is intrinsically linked to the patient´s linguistic and cultural environment, it seems preferable to offer him a questionnaire written in his native language. This allows a broader, fairer, and more adequate use in daily practice, as well as conducting stronger and more relevant research by taking into account Spain's linguistic diversity. (30,31)

The aim was to translate HSCL-25 in the three official languages of Spain: Castilian, Galician and Catalan.

The purpose of this study was to translate HSCL-25 in Galician.

Method

Definition

The HSCL-25 is a self-report questionnaire on the existence and severity of both anxiety and depression symptoms during the previous week, used to identify psychiatric illness in primary care.(45) It includes 25 items: 10 items about anxiety and 15 about depression.(46) The patient is considered as a "probable psychiatric case" if the mean rating on the HSCL-25 is ≥ 1,55. A cut-off value of ≥ 1,75 is generally used for diagnosis of major depression defined as "a case, in need of treatment".(47,48) The HSCL-25 was used in family planning services, among refuges and among migrants.(49–51)

For the translation to retain the same meaning as the original, a Forward-Backward translation(44)(52) was conducted following a formal consensus method: Delphi round. Formal consensus is the most appropriate method when there is a need to reach a solid consensus transparently on a little investigated subject.(53) Delphi procedure, reliable and efficient is used frequently in health care as a rigorous way to reach consensus in defined clinical areas.(54-57) It is a systematic interactive method which involves a panel of experts using iterative procedures. It can be done quickly to make a single convergent final recommendation. This process requires to follow four rules: anonymity of participants (ensures responses' reliability and avoids contamination), iteration (allows participants to refine their views in the light of the progress of the group's work), control feedback (under the responsibility of national investigator (NI)), statistical aggregation of group's responses to allow a quantitative and qualitative analysis of the data. (43)(58-60)

Consents and anonymity

The NI asked the participants for their signed consent, anonymized the expert responses and delivered an identification number for later identification. The name of each expert was not transmitted to others.(43) Only NI's consent was sent to the international investigator senior coordinator. As the study involved no patient, it did not require an ethics committee's decision.

Participants

International investigation team (IIT): The EGPRN French team was familiar with the Delphi methodology. It requested to the NI his consent and voluntary participation in the study and an absence of conflict of interest statement. It ensured that the whole process followed the protocol. It didn't take part of the translation phases or in Delphi rounds. The Forward-Backward translation had to be validated by the daily board of the study, composed of members of the EGPRN, all active within the research process.

National Investigator (NI): The NI was in charge of recruiting translators and experts. He acted between each phase and between two Delphi rounds. He didn't act when a Delphi round was running.

Translators: The NI selected translators to make up two independent translation teams (one for Forward an one for Backward translation respectively). Translators had to be knowledgeable about health care terminology. The Forward translation team involved one member of the GPs research group and one official translator. Galician had to be their native language. The Backward translation team involved one (or two) GP(s) and one official Galician/English translator.(44) The two teams should not have involved the same person.(61)

Experts panel: Initially, 20 to 30 experts were recruited in order to keep at least 15 participants until the end of the last round. The selection criteria for every expert were: being native to Spain and having Galician as their native language; being an English speaker; being in GP practice. Over half had to have teaching or research activities. In order to assess the representativeness of the panel by its diversity, the experts informed their gender, area of practice, years of practice and publications.

Forward Translation

The IIT sent the HSCL-25 original English version to the NI who sent it to the Forward translation team. This team translated HSCL-25 from English to Galician aiming to retain the same meaning as the original.

Delphi rounds

At the beginning of the first round, NI sent by mail the original English version and the Forward translation in Galician with all the rules of procedure. GPs experts received records individually. NI didn't use a mailing list in order to assure anonymity which increases the reliability of responses and avoids contamination (discussion between experts).(62)

Experts expressed their level of agreement on each proposal by using a Likert scale. This Likert scale was an agree/disagree scale of 1 to 9, symmetric, odd, that measured the intensity of their feelings on each proposal, taking into account the maintenance of the meaning between the original and the translation proposal, the

ergonomics and the ease of understanding. Experts rated the proposal from 1 (absolutely no agreement) to 9 (fully agreement) and had to comment when rating less than 7. Consensus was defined for an excerpt's translation when it was rated 7 or above by over 70% of the panel,(63) so it was accepted directly and didn't enter the following rounds; if not (proposal didn't reach consensus), the NI and the Forward official translator synthesized experts comments to propose a new translation proposal for this excerpt. Time between two rounds had to be less than four weeks. The following round began when the NI sent to the experts separately for each proposal that didn't reach consensus: the original English version, the unaccepted proposal, all the experts' comments on this proposal and the new proposal. Experts rated the new proposal in the same way as the first round. The following rounds rolled out in an identical manner. This process was repeated until all excerpts found a consensual translation. The number of rounds was not limited.(58)

At the Delphi procedure's end, there was a consensus on a final Galician version of HSCL-25.

Backward translation

NI sent the final Galician version of HSCL-25 to the Backward translation team who had to translate it into English. The translators should not have the knowledge of the original version (blind-back translation principle). Finally, he sent the English Back-translation to the IIT. (64)

Results

Forward

The NI submitted the questionnaire to one official translator who was knowledgeable about health care terminology and two GP researchers whose native language was Galician. A consensual Forward translation of HSCL-25 was proposed. (Table 2)

Panel

The NI obtained experts consents and asked them for their characteristics. (Table 1)

Twenty experts were recruited for the Delphi procedure. In compliance with selection criteria, they were all GPs, all in General practice, all English speaking.

The panel consisted of 14 (=70%) male and 6 (=30%) female.

Experts all worked in cities > 5000, none worked in small or rural cities.

Clinical experience was analyzed according to years of activity: 0-10y (3/20=15%); 11-20y (3/20=15%); 21-30y (11/20=55%); 31-40y (3/20=15%).

20/20 (=100%) were academic researchers and 19 (=95%) had publications; 3/20 (= 15%) had teaching activity in a General Medicine Training Unit, the other 17/20 (= 85%) worked in Primary Health Centers. In total, 20/20 (=100%) were academic researchers with or without teaching activities.

Delphi Procedure

Two Delphi rounds ran in one month (started and finished in September 2013).

The NI oversaw but didn't take part of the rounds.

The procedure of Delphi rounds was applied: the NI sent the proposed translation with a « single recipient mail » to each expert; every original English excerpt was directly followed by its translation proposal and finally by a Likert scale of 1 to 9.

There were two Delphi rounds to validate the Galician Forward of HSCL-25.

Almost all proposals were accepted in round one. Three excerpts entered the second round, the NI and the Forward official translator synthesized experts comments to propose a new translation proposal for those excerpts. NI sent to the same experts panel (following the same procedure): the original English version, the unaccepted proposal and all the experts' comments on this proposal, the new proposal. Experts rated the new proposal in the same way as for the first round.

Item N° 6 (Trembling): the first proposal was "Trema", present indicative of the verb tremar. The average rate was 7.25/9 and seven experts (35%) rated strictly less than 7. It was apparently an agreement problem. Comments retain the same prefix of "Trem": two proposed "Treme"; one "Treme a miudo", one "Ten tremores", one "Con tremores", one "Ten tremblores" ; one "Sente tremor".

The second proposal was "Ten tremores". In the second round, every expert rated 7 or above (seven, eleven and two experts rated respectively 7, 8 and 9). The consensus was reached with a high level of agreement for this item. The Back-translation was the same as the original version: « Trembling ».

Item N° 10 (Feeling restless): the first proposal was "Séntese inquedanza". The average rate was 7.2/9 and seven experts (35%) rated strictly less than 7. Various synonyms were proposed in comments: "Sente desacougo", "Intranquilo", "Inquietude", "Séntese axitado", "Séntese intranquilo", "Sente inquietude".

The second proposal was: "Séntese inquedo". It was accepted with nine, six and four experts rating respectively 7,8 and 9. One expert rated 5/9 and proposed "sintese axitado ou nervoso ». This second proposal reached consensus with a good level of agreement. The Back-translation was the same as the original version: « Feeling restless ».

Item N° 25 (Sleep disturbance): the first proposal was "Problemas para durmir". The average rate was 7.45/9 and seven experts (35%) rated strictly less than 7.

Two comments were about the possible distinction between « fall asleep » and « sleep maintenance » or « stay asleep » or « wake up and cannot sleep again ». This distinction was not made in the original version and those two situations correspond both to the meaning of « Sleep disturbance ». "Durmir" is a verb which could be translated in « to sleep » and its meaning is closer to « stay asleep » than « fall asleep ». It could have changed the meaning.

One expert proposed to use the interrogative form. Others proposed "Con problemas para durmir", "durme mal", "problemas co sono". The substantive "sono" correspounded to the noun « sleep», it was used in the second proposal.

The second proposal was: "Alteracións do sono". It was accepted in round two with two, ten and six experts who rated respectively 7, 8 and 9. Two experts, who rated 5 and 6 made the same comment: "Durme mal". The Back-translation was « Sleep disorders» which is very close to the original version « Sleep disturbance».

Finally, few comments appeared on the new proposals: and they were widely accepted.

Backward translation

NI sent the final Galician version of HSCL-25 to three translators forming the Backward translation team who translated it back to English. They were knowledgeable about health care terminology. One was a philologist and the two others were GPs. The blind-back translation principle was respected.

Following excerpts had differences between the Original and the Back-translation.

(Original / Backward)

HSCL-25 items: item 3 (Faintness / Weakness); item 5 (Heart racing / Heart pounding); item 12 (Blaming oneself / Blaming yourself for things); item 18 (Thinking of ending one's life / Having thoughts of ending your life); item 24 (Poor appetite / Loss of appetite); item 25 (Sleep disturbance / Sleep disorders).

Answers: 3(Quite a bit / Quite a lot), answer 4 (Extremely / A lot).

Long excerpts all showed differences.

Finally, he sent the English Back-translation to the IIT.

GPs ID No	Gender	English speaker	Years of practice activity	Academic researcher (years)	Publication	Structure	Area of practice	Lower Rate
	M .male	*Y - Yes*			*Y - Yes*	PHC - Primary Health Centre	*1.< 2000*	
							2. 2000-5000	
	F .female	*N - Not*			*N - Not*	TU - Family Practice Training Unit	*3. >5000*	
1	M	Y	28	…	Y	PHC	3	6
2	F	Y	4	1,5	N	PHC	3	5
3	M	Y	20	20	Y	PHC	3	2
4	M	Y	32	30	Y	PHC	3	6
5	M	Y	25	2	Y	PHC	3	6
6	M	Y	8	5	Y	TU	3	4
7	M	Y	32	30	Y	PHC	3	7
8	M	Y	30	20	Y	PHC	3	4
9	M	Y	3	20	Y	TU	3	6
10	M	Y	33	1	Y	PHC	3	6
11	M	Y	14	3	Y	PHC	3	7
12	M	Y	25	…	Y	PHC	3	7
13	M	Y	23	13	Y	PHC	3	7
14	M	Y	30	20	Y	PHC	3	6
15	M	Y	26	23	Y	PHC	3	5
16	F	Y	23	15	Y	TU	3	7
17	F	Y	24	4	Y	PHC	3	6
18	F	Y	23	…	Y	PHC	3	7
19	F	Y	19	5	Y	PHC	3	2
20	F	Y	25	10	Y	PHC	3	1

Table 1: Panel of Family Practice experts

	1	2	3	4	5	6 rd 1	7	8	9	10 rd 1	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25 rd 1		6 rd 2	10 rd 2	25 rd 2
ID N°																													
1	6	9	9	9	9	9	9	9	9	9	9	9	8	8	9	8	9	7	9	9	9	9	9	8	9		9	9	9
2	7	9	8	8	9	8	8	9	8	8	8	7	8	8	9	7	8	8	8	8	8	7	8	8	5		8	7	8
3	8	8	3	3	3	2	8	8	8	2	8	8	8	3	8	8	8	9	8	8	8	8	8	2	3		8	8	8
4	8	8	8	9	7	9	8	9	6	6	8	7	8	8	9	7	9	8	9	8	7	8	8	7	6		8	8	8
5	9	9	9	6	6	6	9	6	9	6	9	6	9	6	9	6	9	6	6	9	6	6	9	6	6		8	8	8
6	9	7	5	5	9	5	5	9	5	5	9	9	9	9	9	4	9	9	7	9	5	9	9	9	5		9	8	6
7	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9		8	8	8
8	9	9	8	9	9	4	8	9	9	8	9	9	9	6	9	8	9	6	8	6	9	9	9	9	9		8	7	8
9	6	6	6	6	6	6	6	6	6	6	6	6	6	6	7	6	7	6	6	7	6	6	6	6	6		8	7	7
10	8	9	9	9	9	7	8	9	8	9	9	7	9	9	9	7	9	7	7	8	8	7	9	9	6		7	9	9
11	9	7	7	7	8	8	9	7	8	8	8	7	8	9	9	8	9	8	8	8	9	8	8	9	9		7	7	8
12	8	8	9	9	8	8	8	9	7	8	9	9	8	7	9	8	9	8	7	8	9	8	9	9	7		8	7	8
13	8	8	8	9	8	9	8	8	8	8	7	8	9	8	9	8	8	8	8	8	9	9	8	8	8		7	7	7
14	8	9	9	9	8	9	9	9	8	8	9	6	9	9	9	7	9	8	8	8	9	8	8	9	9		8	7	9
15	6	9	9	9	9	6	9	9	5	5	5	5	9	5	9	5	9	9	9	5	9	9	9	5	9		7	7	9
16	9	9	8	9	9	8	9	9	9	9	9	9	9	9	9	8	8	9	9	9	9	9	9	9	9		7	9	9
17	9	9	8	9	8	9	9	9	9	8	6	9	9	8	9	9	9	8	9	8	8	8	9	9	9		8	7	8
18	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	6	8	8	8	8	8	8	8	8	8		7	8	8
19	8	8	9	9	4	9	8	9	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	9	9		8	9	9
20	3	1	1	8	8	6	7	8	7	6	3	7	7	2	7	1	7	7	7	4	7	7	7	7	8		7	5	5
Average 1-9	7.75	7.95	7.50	7.95	7.70	7.25	8.10	8.40	7.70	7.20	7.80	7.65	8.35	7.25	8.65	6.90	8.50	7.80	7.90	7.75	8.00	8.00	8.35	7.75	7.45		7.75	7.60	7.95
Rates ≥ 7	80%	90%	80%	80%	80%	65%	90%	90%	80%	65%	80%	80%	95%	70%	100%	70%	100%	85%	90%	85%	85%	90%	95%	80%	65%		100%	95%	90%

Table 2-1: Experts' rates on HSCL-25 items

	Not at all	A little	Quite a bit	Extremely	A	B	C
ID N°							
1	9	9	9	9	9	8	9
2	6	7	8	9	8	5	7
3	9	9	9	9	9	3	3
4	9	6	7	8	7	8	6
5	6	6	6	6	9	6	6
6	5	5	5	5	9	4	9
7	9	9	9	9	9	7	9
8	8	9	6	9	9	9	9
9	9	9	9	8	8	6	7
10	7	9	9	9	7	9	8
11	7	9	8	9	9	9	8
12	8	8	8	9	8	8	8
13	8	9	9	9	8	8	8
14	9	9	8	9	9	9	8
15	5	9	9	9	9	9	5
16	9	9	9	8	9	9	7
17	9	9	9	9	9	8	8
18	8	8	8	8	8	8	8
19	9	9	9	2	9	9	9
20	3	7	7	7	7	7	7
Average 1-9	7.60	8.20	8.05	8.00	8.45	7.45	7.45
Rates ≥ 7	75%	85%	85%	85%	100%	75%	80%

A	Choose the best answer for how you felt over the past week:
B	The HSCL-25 score is based on pencil-and-paper self-report of 25 questions about the presence and intensity of anxiety and depression symptoms over the last week. Participants answer to one of four categories for each item on a four-point scale ranging from 1 to 4.
C	The HSCL-25 score is calculated by dividing the total score (sum score of items) by the number of items answered (ranging between 1,00 and 4,00). It is often used as the measure of distress. The patient is considered as a "probable psychiatric case" if the mean rating on the HSCL-25 is ≥ 1,55. A cut-off value of ≥ 1,75 is generally used for diagnosis of major depression defined as "a case, in need of treatment". This cut-off point is recommended as a valid predictor of mental disorder as assessed independently by clinical interview, somewhat depending on diagnosis and gender. The administration time of HSCL 25 is 5 to10 minutes.

Table 2-2: Experts' rates on other excerpts

	ORIGINAL ENGLISH VERSION	FORWARD	BACKWARD
	Choose the best answer for how you felt over the past week:	Escolla a resposta que mellor describa como se sentiu durante a semana pasada	Choose the best answer to indicate how you felt during the last week
1	Being scared for no reason	Asústase sen motivo	Being scared for no reason / Being suddenly scared for no reason
2	Feeling fearful	Ten medo	Feeling fearful
3	Faintness	Debilidade	Weakness
4	Nervousness	Nerviosismo	Nervousness
5	Heart racing	Palpitacións	Heart pounding
6	Trembling	Ten tremores	Trembling
7	Feeling tense	Séntese tenso	Feeling tense
8	Headache	Dor de cabeza	Headaches
9	Feeling panic	Sente pánico	Feeling panic /Having panic attacks
10	Feeling restless	Séntese inquedo	Feeling restless
11	Feeling low in energy	Sente que lle falta enerxía	Feeling low in energy
12	Blaming oneself	Cúlpase a si mesmo	Blaming yourself for things
13	Crying easily	Chora con facilidade	Crying easily
14	Losing sexual interest	Perda do apetito sexual	Loss of sexual interest
15	Feeling lonely	Séntese só/soa	Feeling lonely
16	Feeling hopeless	Séntese sen esperanza	Feeling hopeless
17	Feeling blue	Séntese triste	Feeling blue
18	Thinking of ending one's life	Pensa en acabar coa súa vida	Having thoughts of ending your life
19	Feeling trapped	Séntese atrapado	Feeling trapped
20	Worrying too much	Preocúpase en exceso	Worrying too much about things / Worrying too much
21	Feeling no interest	Non sente interese por nada	Feeling no interest in anything / Feeling no interest
22	Feeling that everything is an effort	Sente que todo lle supón un esforzo	Feeling that everything is an effort
23	Worthless feeling	Séntese inútil	Feeling worthless
24	Poor appetite	Falta de apetito	Loss of appetite
25	Sleep disturbance	Alteracións do sono	Sleep disorders

Table 3-1: HSCL-25: original version/ Forward version/ Backward version

ORIGINAL ENGLISH VERSION	1.“Not at all”	2.“A little”	3.“Quite a bit”	4.“Extremely”
	The HSCL-25 score is based on pencil-and-paper self-report of 25 questions about the presence and intensity of anxiety and depression symptoms over the last week. Participants answer to one of four categories for each item on a four-point scale ranging from 1 to 4.			
FORWARD	1. “En absoluto”	2.“Un pouco“	3.“Bastante”	4.“Moito”
	A puntuación HSCL-25 baséase nun cuestionario autocumplimentado con lapis e papel, de 25 preguntas sobre a presenza e a intensidade de ansiedade e síntomas depresivos na última semana. Os participantes responden unha de catro categorías para cada ítem, nunha escala de catro puntos que van desde 1 a 4.			
BACKWARD	1."Absolutely not/ Not at all "	2.“A little”	3.”Quite a lot”	4.“A lot”
	HSCL-25 scores are based on a 25-item paper-based questionnaire on the presence and severity of anxiety and other depressive symptoms in the last week. Participants answer one of four categories for each item on a 1-to-4 rating scale.			

Table 3-2: HSCL-25: original version/ Forward version/ Backward version

ORIGINAL ENGLISH VERSION	The HSCL-25 score is calculated by dividing the total score (sum score of items) by the number of items answered (ranging between 1,00 and 4,00). It is often used as the measure of distress. The patient is considered as a “probable psychiatric case” if the mean rating on the HSCL-25 is ≥ 1,55. A cut-off value of ≥ 1,75 is generally used for diagnosis of major depression defined as “a case, in need of treatment”. This cut-off point is recommended as a valid predictor of mental disorder as assessed independently by clinical interview, somewhat depending on diagnosis and gender. The administration time of HSCL 25 is 5 to10 minutes.
FORWARD	A puntuación do HSCL-25 calcúlase dividindo a puntuación total (a suma de todas as preguntas) entre o número de respostas (cuxa puntuación oscila entre 1,00 e 4,00). Úsase de forma habitual para medir o nivel de angustia. Considérase que o paciente é un “caso psiquiátrico probable” se o valor medio do HSCL-25 é >= 1,55. Polo xeral, úsase un valor de corte >= 1,75 para diagnosticar a depresión maior, definida como “un caso que precisa tratamento”. Este valor de corte recoméndase como un predictor válido dun trastorno mental, avaliado independentemente por medio de entrevistas clínicas, aínda que depende en parte do diagnóstico e do xénero. O tempo de realización do HSCL-25 é de 5 a 10 minutos.
BACKWARD	HSCL-25 scores are calculated by dividing the total score (sum of all the questions) by the number of answers (scores ranging from 1.00 to 4.00). The questionnaire is frequently used to measure anxiety levels. Patients with mean rating HSCL-25 scores of 1.55 or greater are considered to be likely psychiatric cases In general, a cut-off score of 1.75 is used to diagnose cases of major or chronic depression defined as requiring medical treatment. This cut-off point is recommended as a strong predictor of a mental disorder, independently assessed through clinical interviews, yet partially dependent on the diagnosis and gender. The HSCL-25 questionnaire takes between 5 and 10 minutes to complete.

Table 3-3: HSCL-25: original version/ Forward version/ Backward version

Discussion

The strength of the study is based on its methodology: the Delphi process adapted for Forward-Backward translation. It can be conducted quickly and it controls confusion bias.

Delphi process with GPs experts performed an expert consensus on Galician translation of the HSCL-25. It must integrate idiomatic expressions, colloquial health phrase and emotional terms in common use in order to be easy to use in GP for practice and research. The Likert scale is an international validated, qualitative and ordinal scale. The ranking 7 or above guaranteed an adherence to the translation.

The HSCL-25 seems to be a very stable questionnaire because almost all excerpts translations were accepted in one round.

Three items were not accepted in round one, however the three new proposals were widely accepted in round two. It assesses that the control feedback was very efficient. Time between the two rounds was less than four weeks, in agreement with Delphi method. Finally, a consensus on Galician translation of the HSCL-25 was reached.

Information bias:

The NI strictly followed the Delphi round method: he sent the same content to all experts. The proposed translation and the rules of procedure were clearly written. All experts rated all excerpts and they wrote comments when rating less than 7. So there was no information bias.

Selection bias:

According to Delphi procedure, GPs experts were sufficient (20 GPs) and selection criteria were strictly followed: they were native from Galicia and Galician was their native language, they were English speaking and were in General Practice.

They all were academic researchers and 15% had teaching activity in a General Medicine Training Unit. Their clinical experience was very high. This very high proficiency guaranteed the Delphi procedure's high quality.

To constitute the panel, experts were chosen to ensure a maximum of heterogeneity, to increase its representativeness.(53)

- Males were more represented with a sex ratio of 2.3/1.

- About geographical heterogeneity, GPs experts were working in different locations, but they were all working in a city> 5000. It can be explained by the high proportion of academic researchers and by Galician health organization. In Spain there is at least one health center in each municipality but GPs work in larger health centers, with usually 4-10 GPs for 6000-15000 patients.

- The years of practice heterogeneity is good although over half of the panel had between 21 and 30 years of activity. According with qualitative studies standards, the panel is qualitatively representative of the Galician GPs population.

Confusion bias:

Delphi process was extensively used in many domains because it does not require any face-to-face meeting and preserve anonymity, so it limits domination effect and conflicts of interest effects.

Forward-Backward is an international consensual process of translation and adaptation of instruments. Particular attention was paid to the selection of translators.

They all have a good knowledge about health care terminology. Forward team consists of two GPs who have Galician for native language, and one official translator. The Backward translation did not involve the same translators as the Forward's. It was done blind by a philologist and two GPs.(44,65)

Participants anonymity was respected during the whole process: the NI sent the proposed translations in « single recipient » mails and then used Identification Numbers for response analysis.

No substantial linguistic or meaning differences had been found between the Original version and both Forward and Back-translation. However, experts' commentaries raised some issues about Forward translation. Furthermore, differences between the Original and the Back-translation appeared. Even if the linguistic translation was reliable, the meaning of some items could be not completely similar.Possible confusion bias could exist, related of the cultural impact. Those aspects will be analyzed with a cultural check.

Conclusion

FPDM study aims to find a diagnostic tool for depression, which can be used all around Europe. The first and the second steps selected HSCL-25 as the best tool to diagnose depression in General Practice setting.

General Practitioners need to get it in their practice languages for both investigation and clinical use. The third step consisted in translating this tool in the language of every country taking part in FPDM study, with the support of European General Practice Research Network (EGPRN). Reliability of each translation is an essential element to make this tool widely usable both in Spain's linguistic areas and on a European scale. This will allow reliable comparisons of the diagnosis assessment of depression and treatment practices. The GPs will exchange more objectively with healthcare authorities and psychiatrists on the prevalence, incidence and treatment of depression in primary care. To meet such objectives, all translations followed the same well-tried formal consensus method. Then, a cultural check will check if each translated excerpt keeps the same meaning as the original and ensures the homogeneity of the various translations.

We performed a consensual translation of HSCL-25 in Galician using a Delphi procedure adapted for a Forward-Backward translation. This procedure aimed to produce the best translation, taking into account cultural differences and Galician special features.

The translation process involved experienced translators and a highly proficient panel of experts. The consensus was reached in two Delphi rounds. Back-translation will be used to perform a cultural check.

During the next step (fourth phase), every national team will test HSCL-25 to ensure its ergonomics in a general practice setting.

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ANNEXES

Annex 1: HSCL-25 Hopkins Symptom Checklist

Département Universitaire de Médecine Générale
22, avenue Camille Desmoulins CS 93837 – 29238 – Brest CEDEX 3
Tél : 02 98 01 65 52 – fax : 02 98 01 64 74

Choose the best answer for how you felt over the past week:

Items		1: “Not at all”	2:“A little”	3:Quite a bit”:	4: “Extremely”
1	Being scared for no reason				
2	Feeling fearful				
3	Faintness				
4	Nervousness				
5	Heart racing				
6	Trembling				
7	Feeling tense				
8	Headache				
9	Feeling panic				
10	Feeling restless				
11	Feeling low in energy				
12	Blaming oneself				
13	Crying easily				
14	Losing sexual interest				
15	Feeling lonely				
16	Feeling hopeless				
17	Feeling blue				
18	Thinking of ending one’s life				
19	Feeling trapped				
20	Worrying too much				
21	Feeling no interest				
22	Feeling that everything is an effort				
23	Worthless feeling				
24	Poor appetite				
25	Sleep disturbance				

The HSCL-25 score is calculated by dividing the total score (sum score of items) by the number of items answered (ranging between 1,00 and 4,00). It is often used as the measure of distress.

The patient is considered as a “probable psychiatric case” if the mean rating on the HSCL-25 is ³ 1,55.

A cut-off value of ³ 1,75 is generally used for diagnosis of major depression defined as “a case, in need of treatment”. This cut-off point is recommended as a valid predictor of mental disorder as assessed independently by clinical interview, somewhat depending on diagnosis and gender.

The administration time of HSCL 25 is 5 to10 minutes.

Annex 2: informed consent (to translate in your language)

Département Universitaire de Médecine Générale

22, avenue Camille Desmoulins CS 93837 – 29238 – Brest CEDEX 3

Tél : 02 98 01 65 52 – fax : 02 98 01 64 74

INFORMATION NOTICE

International Investigator Senior Coordinator

Name: Nabbe Patrice

Address: Département de médecine générale, Faculté de Médecine de Brest, 22, avenue Camille Desmoulins, 29238 Brest cedex 3

International Developer

Département Universitaire de Médecine Générale – 22 avenue Camille Desmoulins - 29238 Brest Cedex 3

National investigator senior coordinator:

Name:
Address:
National developer:

Dear Madam or Sir

You are invited to participate in a survey by A.AUGUSTIN (trainee in general practice, GP…). The department of general practice from BREST. is the national developer of that survey. He is responsible for it and assumes its organization.

Mrs/Mr …….. will explain his/her work to you. If you decide to participate you will be asked to sign a consent form. This signature will confirm that you did agree to participate.

1. Course of study

A Delphi procedure. This Delphi procedure will be fully anonymized and it will be impossible for a study reader to identify you.

2. Potential risk of study

There are no risks associated with your participation in this study

3. Potential benefits of the study

There is no potential benefit to this study

4. Voluntary participation

Your participation to this study is entirely voluntary.

You are free to refuse to participate and to terminate your participation in the study at any time and without incurring any liability or any injury of this fact and without causing consequences.

In this case you must inform the investigator of your decision

In the event that you withdraw your consent, we will conduct a computer processing of your personal data unless written objection on your part.

During the study, your investigator will notify you, if new facts might affect your willingness to participate in the study.

5. Obtaining complementary informations

If desired, Patrice Nabbe or local national investigator (phone number), who can be reached at telephone number: 00 33 674 36 43 22 at any time can answer all your questions about the study.

At the end of the study, and at your request, your investigator will inform you of the overall results of this research.

6. Confidentiality and use of medical or personal data

As part of biomedical research in which the DUMG Brest, Patrice Nabbe and your national investigator offer to participate, a treatment of your personal data will be used to analyse the results of research in light of the objective of that study which was presented to you.

To this end, the data collected, including any survey and the data on your lifestyle will be forwarded to the promoter of the research where the data will be processed in this study.

Those data will be anonymized and their identification will be held with a code number.

Staff involved in the study is subject to professional secrecy.

These data may also, under conditions ensuring their confidentiality be transmitted to the national or European health authorities.

Under the provisions of Law you have the right to access and modify. You also have the right to object to the transmission of data covered by professional secrecy.

If you agree to participate in this study, thank you to complete and sign the consent form. You will keep a copy of it.

Annex 3: Consent Form for each leader

Consent Form (for each leader with department of general practice, Brest, France

Promoter : Département Universitaire de Médecine Générale – 22 avenue Camille Desmoulins - 29238 Brest Cedex

Dr: NABBE Patrice……

……
……

Address: Département de médecine générale, Faculté de Médecine de Brest, 22, avenue Camille Desmoulins, 29238 Brest cedex 3, FRANCE

National leader investigator name

Address: ……..

University:

Asked me to participate in a Forward-Backward translation.

I had time to reflect on my involvement in this study. I am aware that my participation is completely voluntary and that the study will entail no additional cost to my charge.

I can, at any time, decide to leave the study without giving reasons for my decision and that it does without consequences.

I understood that the data collected during the research would be protected in accordance to confidentiality. They can only be accessed by persons subject to professional secrecy belonging to the team-investigating physician, mandated by the promoter.

I accept the computerized processing of personal data in accordance with the data protection act. I have been informed of my right to access and rectify data concerning me.

My consent does not absolve the responsibilities of the organizers of this research. I retain all my rights guaranteed by Law.

Done in two originals

at……, the

dd/mm/yyyy

Name, first name of national leader: Name, first name of the interviewee:

Signature:

Annex 4: Consent Form for each national team

Consent Form (for each national leader with each member of local national team)

Promoter : Département Universitaire de Médecine Générale – 22 avenue Camille Desmoulins - 29238 Brest Cedex 3

Dr:……
……

Address:
……..

Local investigator name

Address:
……..

University:

Asked me to participate in a Delphi consensus.

I had time to reflect on my involvement in this study. I am aware that my participation is completely voluntary and that the study will entail no additional cost to my charge.

I can, at any time, decide to leave the study without giving reasons for my decision and that it does without consequences.

I understood that the data collected during the research would be protected in accordance to confidentiality. They can only be accessed by persons subject to professional secrecy belonging to the team-investigating physician, mandated by the promoter.

I accept the computerized processing of personal data in accordance with the data protection act. I have been informed of my right to access and rectify data concerning me.

My consent does not absolve the responsibilities of the organizers of this research. I retain all my rights guaranteed by Law.

Done in two originals

at……, the

dd/mm/yyyy

Name, first name of investigator: Name, first name of the interviewee:

Signature:

UNIVERSITE DE BREST - BRETAGNE OCCIDENTALE

Faculté de Médecine & des Sciences de la Santé

*****

AUTORISATION D'IMPRIMER

*****

Présentée par Mr le Professeur Jean-Yves LE RESTE

Titre de la thèse :

What is the translation of HSCL-25 in Galician;

A consensus procedure by Delphi-round and Forward-Backward translation.

ACCORD DU PRESIDENT DU JURY DE THESE SUR L'IMPRESSION DE LA THESE

En foi de quoi la présente autorisation d'imprimer sa thèse est délivrée à

Mr AUGUSTIN Arthur, Interne en médecine générale.

Fait à BREST, le 11 sept. 2014

VISA du Doyen de la faculté de Thèse,

A BREST, le 11 sept. 2014

Le Doyen,

Professeur C. BERTHOU

UNIVERSITÉ DE BRETAGNE OCCIDENTALE FACULTÉ DE MÉDECINE DE BREST

Le Président du Jury

Professeur J.Y. LE RESTE
Directeur du Département
Département de Médecine Générale

AUGUSTIN Arthur – What is the translation of HSCL-25 in Galician; A consensus procedure by delphi-round and Forward-Backward translation. 37 pages, tables, annexes.
Thèse Medecine : Brest 09/14

Résumé

Introduction : Les médecins généralistes européens sont le premier recours des patients dépressifs. Les patients de plus de 50 ans multi-morbides sont plus à risque d'épisodes dépressifs. Les variations interindividuelles et interculturelles peuvent modifier l'expression des symptômes. En soins primaires, peu d'outils diagnostiques sont adaptés et utilisés. L'étude Family Practice Depression and Multimorbidity (FPDM) de l'European General Practice Research Network (EGPRN) a pour objectif de sélectionner un outil diagnostique de la dépression en médecine générale. Des recherches européennes collaboratives entre médecins généralistes de différents pays et entre médecins généralistes et psychiatres pourront être réalisées. Les deux premières étapes ont sélectionné la Hopkins Symptom Checklist en 25-items (HSCL-25) comme la plus appropriée selon les critères d'efficacité, de reproductibilité et d'ergonomie versus DSM.

Objectif : L'objectif était de traduire la HSCL-25 en Galicien sans perte de sens mais cette traduction devait être compréhensible par les médecins et les patients, en prenant en compte les particularités culturelles et linguistiques galiciennes.

Méthode : Une procédure Delphi adaptée avec traduction Aller-Retour a été utilisée. Une traduction de l'Anglais au Galicien a été soumise par procédure Delphi à un panel d'experts en soins primaires. La traduction retour a été réalisée en aveugle de l'original.

Résultats : Le panel d'experts répondait aux critères d'inclusion. La traduction galicienne a été validée après deux tours. La traduction retour en anglais a été produite.

Discussion : Le choix d'une méthode de traduction Aller-Retour par procédure Delphi adaptée et la qualité du panel d'experts garantissent une traduction galicienne validée et fiable de la HSCL-25. La prochaine étape est une analyse culturelle de la traduction qui assurera la similitude sémantique entre la version originale et la traduction.

Abstract

Introduction: General Practitioners (GPs) are the first port of call for depressive patients in developed countries. The multi-morbid patients over 50 years are more at risk. Inter-individual and intercultural variations may change the symptoms expression. Few diagnostic tools are adapted and used by GPs. Family Practice Depression and Multimorbidity (FPDM) study by European General Practice Research Network (EGPRN) aims to select a depression diagnostic tool in primary care to undertake collaborative research involving GPs and Psychiatrists throughout Europe. The two previous steps of FPDM found that the Hopkins Symptom Checklist in 25-items (HSCL-25) was the most appropriate tool according to effectiveness, reproducibility and ergonomics criteria, versus DSM.

Objective: This study aimed to translate HSCL-25 in Galician, keeping its meaning. This translation must be understandable by practitioners and patients, according to Galician cultural and linguistic features.

Method: A Delphi method adapted for a Forward-Backward translation was used. The Forward-translation from English to Galician was submitted by Delphi procedure to a panel of primary care experts. The Back-translation was performed following the blind back-translation principle.

Results: The inclusion criteria of panel were followed. The Forward Galician translation was accepted after two rounds. English back-translation was produced blind.

Discussion: The Forward-Backward translation by Delphi method was effective to translate the HSCL-25 to Galician. The experts panel quality ensured a validated and reliable Galician translation. The following step will consist in a cross-cultural check. Similarity of interpretability between the Original and the Back-translation will be analysed.

MOTS CLES:
Depression
Translation
HSCL-25
Delphi
Galician

JURY:

Président : Pr. JY LE RESTE

Membres : Dr. P NABBE
Pr. B. LE FLOC'H

DATE DE SOUTENANCE :
25 septembre 2014

ADRESSE DE L'AUTEUR :
1 Rue Rochefort, 29200, BREST